Column E Explanations – 7 Dogs

1. **Registration Number:** 84-R-0072

2. **Number of animals used in this study:**

   A total of 12 dogs were used on this study. Seven dogs are reported here as a Category E, 3 dogs are reported as Category C, and 2 animals are reported as Category D as they received treatment for study complications.

3. **Species of animals used in this study:** Canine

4. **Explain the procedure producing pain or distress:**

   The purpose of this study was to evaluate the tolerability of two test articles and vehicles delivered as a subcutaneous injection. In this acute maximum tolerated dose (MTD) study, pain, distress, morbidity, or mortality were listed as possible complications. No animals died or were moribund. Three animals did not experience clinical signs indicating pain and distress and are listed in Category C. Seven animals experienced short term pain and distress following injection. Signs of pain and distress included vocalization, biting at injection site, and agitated behavior, and only lasted a short period following dose administration. In response to the clinical signs observed the administration of the high dose was cancelled. Two animals developed necrotic tissue at the sight of injection and required medical intervention (analgesia, antibiotics, and wound cleaning). These animals are listed in Category D.

5. **Scientific or regulatory justification for withholding of pain/distress relief:**

   Determination of an accurate MTD and/or clinical signs associated with high doses requires that animals are alert and conscious, thus analgesics were withheld in the acute phase of dosing. Close observation identified a high dose that, while tolerated, resulted in clinical signs severe enough that higher doses were not tested.

Column E Explanations – 104 Cats

1. **Registration Number:** 84-R-0072

2. **Number of animals used in this study:**

   A total of 104 cats were used in two studies. The first study included 62 cats and the follow-up study included 42 cats.

3. **Species of animals used in this study:** Cats

4. **Explain the procedure producing pain or distress**

   The objective of these two studies was to evaluate the efficacy of ocular application of anti-viral eye drops on experimentally induced ocular feline herpesvirus-1 (FHV-1) infection. All animals were induced with FHV-1 to develop ocular signs of infection to evaluate the test article or vehicle control eye drops. All animals experienced conjunctivitis, blepharospasms, and ocular discharge.

5. **Scientific or regulatory justification for withholding of pain/distress relief:**

   The treatment for these clinical signs would have been contraindicated in the study as it would have masked the clinical signs used to determine the efficacy of the test article versus vehicle control.